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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,063	10/13/2000	Michael J. Natan	SURR-30	1277

7590

10/04/2002

Barry J Swanson
Swanson & Bratschun LLC
1745 Shea Center Drive Suite 330
Highlands Ranch, CO 80129

EXAMINER

CROSS, LATOYA I

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 10/04/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/688,063

Applicant(s)

NATAN ET AL.

Examiner

LaToya I. Cross

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

This Office Action is in response to Applicants' amendment filed June 26, 2002 and entered as Paper No. 12. Claims 1-63 are pending.

Withdrawal of Rejections from Previous Office Action

- The rejection of claims 1-8 under 35 USC 102 over Markell et al is withdrawn in view of Applicants' amendment to state that the particles are free standing.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 15-20-24 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,280,618 to Watkins et al (hereinafter Watkins et al '618).

Watkins et al '618 teach assaying for different analytes in a single biological sample by using a plurality of magnetically responsive microparticles having an assay reagent coupled thereto. The microparticles are free standing particles and the assay reagents serve as extraction phases coupled to the microparticles. See abstract. Watkins et al '618 teach that the microparticles are classified into groups differing in a selected differentiation parameter, allowing each group of microparticles to be distinguishable from another group (col. 5, line 61 - col. 6, lines 8). Parameters such as particle size, fluorescence and light scattering/emission

Art Unit: 1743

abilities are used to distinguish the microparticles, as recited in claims 15-19. Once contacted with the microparticles, the sample is analyzed for target analytes by flow cytometry, which may be a quantification type analysis. As an assay reagent (extraction phase), Watkins et al '618 teach the use binding proteins. As analytes, Watkins et al '618 teach targeting antigens (col. 19, lines 7-9 and lines 34-37), as in claims 23 and 24.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 103 in view of the teachings of Watkins et al '618.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watkins et al '618 in view of Michael et al (Randomly Ordered Addressable High Density Optical Sensor Array).

The teachings of Watkins et al '618 are detailed above.

Watkins et al '618 fail to teach:

- 1) any particular number extraction probes (claims 12, 25-27, 41, 42, 53, 56 and 57);
- 2) combinatorially-derived extraction phases (claims 6, 36 and 46);
- 3) position addressable arrays (claim 10 and 59); and
- 4) encoded extraction probes (claims 9 and 54);

With respect to the number of extraction probes, Watkins et al '618 teach that the microparticles can yield an individual result for analytes. Thus, it would have been obvious to one of ordinary skill in the art to use a multiplicity of extraction probes to allow for multiple

Art Unit: 1743

analytes to be determined. The skilled artisan would recognize that in analyzing complex samples, a greater number of extraction probes may be used to increase the likelihood that all of the different analytes are separated and analyzed.

With respect to using combinatorially-derived extraction phases, position addressable arrays and encoded extraction probes, Michael et al teach such. Michael et al teach sensors made by immobilizing different reactive chemistries on the surfaces of microspheres. These different reactive chemistries allow for a "large, diverse sensor library". The microspheres are encoded and are allowed to have individually unique sensing patterns that can be registered on a detector and identified. The microspheres are then ordered in addressable sensor arrays. Michael et al teach that such encoding and ordering allows for multi-analyte sensing and alleviates the need for identification of each location containing a microsphere and the need for calibration of each sensor. Michael et al also suggest position addressable arrays where the identity of the microspheres is determined by its location in the array, although such is not preferred.

It would have been obvious to one of ordinary skill in the art to use combinatorily-derived chemistries on the microparticles of Watkins et al to allow for analysis of an infinite number of analytes in a sample. Further, it would have been obvious to one of ordinary skill in the art to arrange array of extraction probes either by position addressably or by encoding. Both methods provide a manner for identifying the extraction probes and making the analysis of the samples a more ordered and simple.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Watkins et al '618 and Michael et al.

Art Unit: 1743

Response to Arguments

3. Applicant's arguments filed June 26, 2002 have been fully considered but they are not persuasive. Regarding the Michael reference, Applicants argue that the reference teaches against position addressable array. In response, it is noted that Michael et al prefer encoding as an identifying means, however, the reference still suggest identifying by location/position, although not preferred. MPEP 2141.02 states that the prior art as a whole must be considered, even teachings that might lead away from the present invention. Also, non-preferred embodiments are to be considered as valid teachings in taking the prior art as a whole. See *In re Gurley*, 27 F.3d 551.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1743


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360.

The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC
September 27, 2002


Jill Warden
Supervisory Patent Examiner
Technology Center 1700